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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/576,597	05/22/00	VOORHEES J	1718-009A

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EXAMINER	
KIM, V	
ART UNIT	PAPER NUMBER
1614	2

DATE MAILED: 05/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)	
	09/576,597	VOORHEES ET AL.	
	Examiner	Art Unit	
	Vickie Y. Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19

is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-9 are rejected under 35 U.S.C. 102(b/e) as being anticipated by Oliver (US 5,869,062), Murad (US 5,804,594), Ramamurthy et al (US 5,998,390) or Liu et al.(US 6,080,393).

The claims read on a composition comprising a combination of a non-retinoid inhibitor of a dermal matrix-degrading enzyme(e.g. ap-1 inhibitors, NF-kB inhibitors elastase inhibitors or adhesion antagenists etc); and an active ingredient selected from the group consisting of conventional acne treating agent(e.g. comedolytics, antibacterials, retinoids, glucocorticoids etc). the claims 3-4 additionally require either a carrier or systemic application. Claims 5-9 are further limited to a retinoid, an antibacterial or benzoyl peroxide, an antioxidant or a combination of an MMP inhibitor and a neutrophil elastase inhibitor as the said inhibitor.

Firstly, Oliver teaches the claims 1-3 and 5-9 , a acne treating composition comprising antibacterial, benzoyl peroxide and ascorbic acid with a pharmaceutically acceptable carrier: see full text, especially exemplified composition at column 3).

Secondly, Murad teaches the claims 1-5 and 8-9 a pharmaceutical composition for various skin conditions basically comprising a primary antioxidant component in an amount sufficient to substantially inhibit the formation of collagenase and elastase, ascorbic acid (see abstract); and further includes vitamin A palmitate(effective acne and wound healing agent-see column 1, line 50-53), N-acetyl cysteine(see column 6, lines 24-30), quercetin, vitamin E (as an antiinflammatory agent-see column 1, lines 59-61 & abstract); and the pharmaceutically acceptable carrier(s) formulated for various pharmaceutical applications, especially oral administration is preferred(see column 8, lines 37-57).

Thirdly, Ramamurthy et al teach the claims 1-4, 6 and 8, a synergistic combination of tetracycline analogs(anti-acne/antibacterials/MMP inhibitors) and bisphosphonates(Elastase inhibitor); see full text, especially column 7-9 and claims.

Lastly, Liu et al teach the claims 1-4 and 7-9, an acne and other skin condition treating composition comprising retinoids, antioxidant e.g. vitamin D, E, C(ascorbic acid), and further includes corticosteroids, azole compounds and so on. All the critical elements are taught by this cited reference. See example 3 at column 10.

The claims are drafted with very broad terms. The claims had been read in light of specification wherein the species has been defined or exemplified. For instance, Vitamin C(ascorbic acid) is one of preferred species used as antioxidant(see applicant's instant specification; page 23) which is an inhibitor of dermal matrix degrading enzymes. Since it is inherent feature where one skilled artisan could recognize or envisage easily without the additional documents(notoriously known), and the claims should be encompassed by the cited references. It is also applied to other species such as vitamin D, corticosteroid, N-acetyl cysteine

,quercetin and vitamin A(retinoids) inherently possess MMP inhibiting activity(see US 5,837,224).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teronen et al. (US 5,652,227) and Ramamurthy et al (US 5,998,390).

The claims read on a method of treating acne, comprising the steps of oral administration of an active acne agent and topical application of a non-retinoid, non-glucocorticoid inhibitor of a dermal matrix-degrading enzyme to acne-affected skin.

Teronen et al teach a method of treating acne using bis-phosphonates which is a MMP inhibitor; see abstract. They also teach a combination therapy with other drugs normally used in connection with the said disease; see column 4, lines 16-18.

Ramamurthy et al teach a synergistic combination of tetracycline analogs and bisphosphonates used for inhibiting the production and activity of proteinases including MMP's serine proteinases and related enzymes which could mediating various pathological conditions including acne; see abstract and column 7-8.

The combination of these cited references teach a synergistic composition (or combination where they are not necessarily formulated in a composition-see column 8, lines 30 and column 10) of tetracycline and bisphosphate could be utilized in acne therapy effectively in

adjunction to normal acne therapy. It is again that the inherent features would render the claims patentable when the intended use (i.e.treatment for acne) are encompassed by the cited references.

Applicant's claim may differ because it require specific route administration of each component, antioxidant.

However it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teaching of these references combined because it is within the level of any skilled artisan to combine with antioxidant to improve the efficacy wherein combination therapy is very popular in acne therapy with antioxidant and other active agents) and modify the route of application to find the best combination fits in patient's need and for most effective therapy.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,998,394 in view of 5,837,224 and 6,130,254.

Claims read on a method of treating acne and a composition comprising a combination of a non-retinoid inhibitor of a dermal matrix-degrading enzyme(e.g. ap-1 inhibitors, NF-kB inhibitors elastase inhibitors or adhesion antagenists etc); and an active ingredient selected from the group consisting of conventional acne treating agent(e.g. comedolytics, antibacterials, retinoids, glucocorticoids etc).

The US'394 teaches a composition for various skin conditions including acne ,comprising Vitamin D3, retinoids whereas US'224 teaches Vitamin D3 and retinoid are MMP inhibitors and US'254 teaches that vitamin C or other MMP inhibitors could be substituted for treating same skin conditions. One would have motivated to make a modification to extend the availability of each ingredient and enhance the efficacy with lower dose of each ingredient which would result in less side effects by combination of active acne agents and inhibitors of dermal matrix degrading enzymes.

Conclusion

7. All the pending claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
May 4, 2001

William Jarvis
Primary examiner
Art unit 1614